Estimating Daily Soil Ingestion Rates

Initial soil ingestion estimates provided a daily soil ingestion averaged over a time period.[34] This rate was simply the total estimated quantity of soil ingested divided by the total number of days observed. Thus, this did not offer any insight [into] the nature of variation within a subject [on] different days. In order to provide more realistic estimates of soil ingestion over a longer time frame than the study's duration, it is necessary to obtain estimates of soil ingestion on each day of the study for each subject.[35] These findings could then be modeled in order to estimate exposure over any duration desired.

Several years ago, we developed a novel method to estimate an individual day's soil ingestion for subjects and then used these values to estimate soil ingestion over a 365-day period.[36] The estimation of daily soil ingestion and subsequent extrapolation over a year were instructive because they provided the opportunity to estimate the number of days in a year that various proportions of the population would be predicted to ingest amounts of soil of interest (e.g., ≤200 mg, ≥500 mg, ≥1,000 mg, ≥5,000 mg, or ≥10,000 mg). As seen in Table 4, this exercise predicted that 33 percent of the children would have 1 to 2 days per year when they would ingest more than 10 g of soil while 16 percent of the children would ingest more than 1,000 mg on 35 to 40 days in a year. These values are model estimates based on the daily soil ingestion estimates and are likely to overestimate soil ingestion.[37] However, such daily estimates could be used with other models with different assumptions and therefore yield other predictive outcomes. The principal point is that with the capacity to provide daily estimates the risk assessor has greater capacity to address more biologically relevant exposure periods that are highly relevant for site-specific risk assessments.

Table 4. Estimated Percent of Children With Soil Ingestion Exceeding Daily Rates for Given Time Periods Per Year

Estimated No. of Days/Year With Soil Ingestion	Daily Rate of Soil Ingestion				
	>200 mg	>500 mg	>1 g	>5 g	>10 g
1-2	86	72	63	42	33
7-10	72	53	41	20	9
35-40	42	31	16	1.6	1.6

Source: Stanek and Calabrese, 1995

Soil Particle Size That Children Ingest

Many contaminants are associated with specific particle sizes found in soil.[38] Researchers typically have determined concentrations of trace elements in soil ingestion studies sieved to a diameter of 2 millimeters (mm). Knowledge of the soil particle sizes that children ingest may be a critical determinant in the exposure assessment process. In order to determine the particle size ingested, it is necessary to have two groups of tracers in soil: one whose concentration in soil is independent of particle size; the other being tracers whose concentration is particle-size dependent. In fact, tracers such as aluminum, silicon, and titanium are particle-size independent while the concentrations of cerium, lanthanum, and neodymium are highly dependent on particle size.[39] In the case of these three particle-size dependent trace elements, their concentrations increase markedly as the particles become finer (i.e., smaller in diameter). Moreover, as the particle size diminishes from 2 mm to 250 micrometers (μm) in diameter, the concentration increases from 2.5- to 4-fold for these three tracers. Because particles in the range of 50-100 μm in diameter are typically the ones that adhere to children's fingers,[40] and that children place their fingers frequently in their mouths,[41] children may be likely to ingest soil of relatively fine particle size.

Soil particles at a 2 mm diameter have a concentration of cerium, lanthanum, neodymium of one-half to one-quarter of that in the less than 250 μm range.[42] As a result, soil ingestion estimates are expected to be 2- to 4-fold higher for cerium, lanthanum, and neodymium when estimates use the 2 mm particle size. Once we started estimating soil ingestion according to particle size (50, 100, and 250 μm), the intertracer reliability of soil ingestion estimates markedly improved. The key feature in estimating particle size ingested is to determine the particle size where the intertracer variability is minimized to the greatest extent. This method works very well in the zone from 2 mm to 250 μm. There does not appear to be significant further concentration of the above three tracers (lanthanum, cerium, neodymium) at particle sizes below 250 μm (i.e., down to 50 μm diameter).[43] The available data suggest that the children were ingesting the finer particles but it was not possible to add further significant precision below the 250 μm diameter particle size.

In the particle size methodology, it is necessary to have tracers (i.e., gold standard tracers) that do not vary by particle size. These tracers will provide reliable estimates of soil ingestion regardless of the particle ingested. However, because contaminant concentrations may differ by particle size, it is valuable to include particle-size dependent tracers along with the gold standard tracers in soil ingestion studies. However, it would be ideal if tracer elements were available

34. *See* Binder et al., *Estimating Soil Ingestion*, *supra* note 11; Clausing et al., *A Method for Estimating Soil Ingestion in Children*, *supra* note 16; Calabrese et al., *How Much Soil*, *supra* note 9; Davis et al., *Quantitative Estimates*, *supra* note 10.

35. *See* Edward J. Stanek III et al., *A Caution for Monte Carlo Risk Assessment of Long-Term Exposures Based on Short-Term Exposure Study Data*, 4 HUM. & ECOLOGICAL RISK ASSESSMENT 409-22 (1998).

36. *See* Stanek & Calabrese, *Daily Estimates*, *supra* note 25.

37. *See id.*

38. Steven C. Sheppard & Evenden, *Ecosystem Processes: Contaminant Enrichment and Properties of Soil Adhering to Skin*, 23 J. ENVTL. QUALITY 604-13 (1994).

39. *See* Edward J. Calabrese et al., *The Effect of Particle Size on Soil Ingestion Estimates*, 24 REG. TOXICOLOGICAL PHARMACOLOGY 264-68 (1996).

40. *See* Sheppard & Evenden, *supra* note 38.

41. *See* Edward J. Stanek III et al., *Prevalence of Soil Mouthing/Ingestion Among Healthy Children Aged 1 to 6*, 7 J. SOIL CONTAMINATION 227-42 (1998).

42. *See* Calabrese et al., *Soil Ingestion*, *supra* note 16.

43. *See* Edward J. Stanek III et al., *Soil Ingestion Estimates for Children in Anaconda Using Trace Element Concentrations in Different Particle Size Fractions*, HUM. & ECOLOGICAL RISK ASSESSMENT (forthcoming 1998).

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DIALOGUE

Soil Ingestion Estimation in Children and Adults: A Dominant Influence in Site-Specific Risk Assessment

by Edward J. Calabrese and Edward J. Stanek III

Editors' Summary: Over the past couple of decades, as awareness of hazardous waste contamination has grown, the exposure of children and adults to hazardous wastes via ingestion of contaminated soil has emerged as a dominant concern in risk assessment. This Dialogue summarizes the results and implications of a multiproject research endeavor to estimate soil ingestion in children and adults. The authors begin by explaining how soil ingestion studies are conducted. They also discuss how to differentiate among soil ingestion studies of different quality. They then summarize how to use soil ingestion studies to glean insights into the more critical aspects of soil ingestion that relate to risk, such as how to differentiate dust ingestion from soil ingestion, how to estimate soil ingestion on different days, and how to average ingestion over multiple days. The authors note that while researchers have performed several studies on soil ingestion by children, significant gaps remain in the knowledge on this subject. Studies evaluating differences in soil ingestion by comparing regions of the country, by comparing urban and rural populations, and by comparing seasons of the year remain to be performed. The authors further point out that studies on soil ingestion by adults are limited and that considerable uncertainty still exists in this area. Thus, while this project has resulted in significant gains in risk assessment, there are more questions to be resolved.

The risk assessment process has always included a prominent role for exposure assessment. Traditionally, exposure assessment incorporated information on the amount of water people drink, the number of cubic meters of air people inhale per hour or per day, and the amount of foods people consume.[1] However, exposure due to ingestion of contaminated soil has emerged over the past decades as a dominant concern, especially with respect to soil contamination for tightly bound agents such as dioxin, polychlorinated biphenyls, lead, and numerous pesticides.[2] In such cases, the obvious focus has been on young children because of their playful characteristics, high hand-to-mouth activity, and reliance on caregiver attention rather than themselves for hygiene practices. Thus, it came to be believed that young children might receive substantial exposure to soil contaminants via soil and dust ingestion.[3] So substantial was this concern that it came to dominate the initial risk assessment activities at Times Beach, Missouri,[4] where the U.S. Environmental Protection Agency (EPA), assuming that children ingested 10,000 milligrams per day (mg/day) of soil,[5] purchased the homes of residents because of the fear of cancer risks from dioxin contamination.

With the increased awareness of hazardous waste con-

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1. *See* U.S. EPA, EXPOSURE FACTORS HANDBOOK (1989) [hereinafter 1989 EXPOSURE HANDBOOK]; U.S. EPA, EXPOSURE FACTORS HANDBOOK (1996) [hereinafter 1996 EXPOSURE HANDBOOK].
2. *See* Dennis J. Paustenbach, *A Survey of Health Risk Assessment*, *in* THE RISK ASSESSMENT OF ENVIRONMENTAL AND HUMAN HEALTH HAZARDS: A TEXTBOOK OF CASE STUDIES 296-328 (1989).
3. *See* 1989 EXPOSURE HANDBOOK, *supra* note 1; 1996 EXPOSURE HANDBOOK, *supra* note 1.
4. The community of Times Beach, Missouri, was contaminated with large amounts of dioxin as a result of the improper disposal of waste oils. So substantial was the contamination that EPA purchased numerous homes and moved families from the area, thereby making that area the object of considerable investigations of dioxin soil contamination.
5. *See* Renate D. Kimbrough et al., *Health Implications of 2, 3, 7, 8-TCDD Contamination of Residual Soil*, 14 J. TOXICOLOGY & ENVTL. HEALTH 47-93 (1984).

tamination in the 1980s, resolution of how much soil and dust children ingest suddenly became important to determine. In the summer of 1986, our research group at the University of Massachusetts received an award from Syntex Agribusiness, Inc., as a result of their involvement in the Times Beach dioxin contaminant case, to estimate how much soil children ingest. This study proved to be the start of a now 12-year multiproject endeavor to estimate soil ingestion in children and adults. This Dialogue summarizes the results and implications of this research to date.

Brief Summary of What Has Been Learned

First, let's briefly summarize what we have learned. Most importantly, after assessing more than 1,200 possible child soil ingestion days, it is quite clear that most children on average did not ingest an amount of soil even close to the initial assumption of 10,000 mg/day that the Times Beach risk assessment assumed. The average child aged 1 to 4 years has been observed to ingest soil in the 30-60 mg/day range. After several soil ingestion studies on children became available, EPA soon reduced the daily soil ingestion estimate for risk assessment purposes from 10,000 mg to 200 mg, calling that value the upper 95 percentile. However, beyond this important general refinement, there also emerged issues of protection of the soil pica child[6] who may ingest copious amounts of soil on certain days as well as adult soil ingestion values. This Dialogue summarizes (1) how soil ingestion studies are conducted; (2) how to differentiate among soil ingestion studies of different quality; and (3) how to utilize soil ingestion studies to provide insights on more critical aspects of soil ingestion that are related to risk, such as what size of soil particles children ingest, how to differentiate dust ingestion from soil ingestion, how to estimate soil ingestion on each day in addition to average ingestion over multiple days, and how much soil human adults and animals ingest.

How Soil Ingestion Rates Are Estimated

Mass-Balance Studies

Soil ingestion rates have been estimated by the use of naturally occurring multiple inorganic tracers such as silicon, aluminum, and titanium in the soil that are believed to be both low in the diet and poorly absorbed by the gastrointestinal (GI) tract and therefore excreted in feces. Once the tracer values are determined for the fecal samples, an estimate is made as to how much ingested soil would have been required to achieve that level of specific tracer in the fecal sample. This, of course, would require that soil tracer concentrations where the child played (i.e., usually the yard outside the child's home) and household dust tracer concentrations also be determined.

Unfortunately, the source of trace elements in feces is not solely soil and dust. Trace elements also occur in food. Ideally, soil ingestion studies should use what is called a mass-balance study protocol in which duplicate samples of all ingested items (e.g., food, medicines, and vitamin pills) during each day of the study are obtained along with daily excretory samples. The estimation of tracers ingested is subtracted from fecal levels to prevent overestimation of the soil ingestion estimates. Typically, it is assumed that food has been ingested one day before the collection of fecal samples under the assumption that passage through the GI tract requires an average of about 24 hours. In this way, there is an effort to match input (i.e., food consumption) and output (i.e., fecal samples) of tracers over the same period of days. In order to reduce the possibility of food input—fecal output misalignment error, the soil ingestion studies are usually conducted for multiple consecutive days (e.g., up to a seven-day period) with the assumption that the longer the study the less chance for significant error (i.e., the greater the likelihood that the child's input-output of tracers from food will achieve a balance).

The Importance of Intertracer Consistency

One of the powerful features of using multiple soil tracer agents to estimate soil ingestion rates is that each tracer theoretically provides an independent estimate of the same behavior (i.e., how much soil the child ingested). In this way, considerable confidence in a soil ingestion estimate may be achieved when multiple tracers offer similar estimates for the same day of a particular child. For example, if a child ingested negligible soil on days 1 and 3 of a study, but copious amounts of soil on days 2 and 4 of the same study, this would be discerned as troughs and waves of soil tracers excreted in the fecal samples (i.e., very low quantities on days 1 and 3, and very high quantities on days 2 and 4). In fact, such waves and troughs are commonly observed within our data on soil ingestion and provide discernable individual daily patterns of soil ingestion variation for an individual. However, the key feature is that high intertracer consistency *on the same day* provides the critical foundation for the establishment of confidence in the conclusion that the studied child ingests low amounts of soil on days 1 and 3, and high amounts of soil on days 2 and 4. Alternately, doubt may occur when estimates differ widely.

Even though multiple tracers offer independent estimates of soil ingestion, decisions need to be made over how to determine what the best soil ingestion estimate for a child is if the estimates of the individual tracers differ. For example, the amount of soil ingested could be estimated by the average of all the independent tracer values for a particular time period (e.g., a day). It would be possible to incorporate such values into an uncertainty analysis because each value represents the input for a distribution of possible values. If estimates differ widely for different trace elements, this challenges the investigators to address the causes of such lack of intertracer agreement (e.g., differentiating error from normal variation).

Validation of Soil Ingestion Study Protocol

Validation of the above soil ingestion methodology is critical in order to have confidence in any soil ingestion estimation. For this reason, we have conducted experimental studies in which adult subjects were blindly administered soil daily in capsules ranging from 20 to 500 mg in order to assess whether we could accurately estimate the quantity of soil ingested using the identical study design followed by the children in our respective studies. These so-called adult validation studies revealed that only those tracers with a

6. A "soil pica child" refers to a child that ingests substantially more soil than the average child.

high soil-to-food concentration ratio perform well (i.e., a high signal (soil) to noise (food) ratio); that is, they display a high degree of precision of recovery (100 percent ± 10 to 20 percent). Some early tracers such as barium and manganese that have relatively low soil-to-food ratios performed quite poorly on soil ingestion validation studies.[7] This lack of precision of recovery with barium and manganese in adult validation studies suggests that these tracers have high potential for error in their estimates. In fact, these tracers often result in soil ingestion estimates that differ dramatically from soil ingestion estimates based on other tracers. In contrast, agents such as aluminum and silicon generally have high soil-to-food ratios. Using such adult validation studies, we have been able to estimate the precision of recovery in adults for all tracers and apply that model to mass-balance soil ingestion studies and develop the equivalent of a soil ingestion detection capacity. These results allow investigators to estimate whether their study design had the capacity to detect the reported soil ingestion rates reliably for each tracer for any day or over a multiday period.[8] This methodology is conceptually similar to the approach of analytical chemists as they estimate the detection level of a chemical in any medium.

Using this soil ingestion detection method, we have been able retrospectively to assess the precision of tracer recovery and detection levels of all tracers used in mass-balance studies. The level of detection depends on the amount of a trace element ingested in food relative to that present in a given quantity of soil. Because both food and soil trace element concentrations may differ geographically, the reliability of a trace element also may differ from study to study. It is interesting to note that a number of the reported estimates in our initial study (barium, manganese, vanadium, and yttrium)[9] and another study (aluminum, silicon, and titanium)[10] were, in fact, below the estimated level of detection (as defined by the capacity to detect this value with 95 percent confidence). This means that the soil ingestion estimates reported for these tracers were probably not seen with sufficient confidence to provide reliable estimates. Such estimates of precision of recovery and detection capacity of soil ingestion rates represent an important conceptual advance and provide a means to permit investigators and risk assessors to determine whether the soil ingestion values that are estimated are likely to be reliable. Before this development, investigators simply presented their findings without being able to determine the precision of recovery and the level of detection capacity their study had.

One of the striking features of the adult validation studies is that most tracers, including the poorest performing ones (i.e., those having the lowest food-to-soil ratios), are able to provide reliable estimates of soil ingestion when the daily exposure approaches 500 mg/day. However, as the daily soil ingestion quantity is reduced to 100 mg/day and further to 20 mg/day, the capacity to estimate soil ingestion rates reliably rapidly falls off with only those tracers having the highest soil-to-food ratios being able to provide reliable estimates. These findings also suggest that the soil ingestion detection capacity will vary by day depending on the quantity of tracers consumed in the diet that day.

A New and Important Source of Error

Another challenge in human soil ingestion studies is that some of the tracers may be ingested from a non-food, non-soil source (e.g., as tracer components of newspaper ink) and yet contribute to fecal concentrations of the tracers. In this case, such contributions would constitute positive error (i.e., inflating the soil ingestion estimate of that subject based on a specific tracer). This type of positive error (from non-food, non-soil source), which we call "source" error, contributes to a lack of intertracer agreement in soil ingestion estimates for an individual. The magnitude of the error may be very large and is believed to have contributed to the extraordinarily high values seen with titanium in all published soil ingestion studies. The initial studies of Susan Binder et al. in 1986 reported soil ingestion rates that were severalfold higher for titanium than for aluminum and silicon for the same children.[11] Such intertracer disagreements are now believed to have been highly affected by source error. In fact, all independently conducted soil ingestion studies have shown remarkable consistency with their titanium values. That is, the soil ingestion estimates based on titanium are markedly higher on average than those based on aluminum and silicon.

Such recognition of source error and how to deal with it effectively in a nonbiased manner has presented a strong challenge for the interpretation of soil ingestion studies. More specifically, the challenge is distinguishing source error from actual soil ingestion properly. Similar source error has also been reported for vanadium,[12] neodymium, lanthanum, and cerium.[13] In one particular case, the positive source error was so great from vanadium that the subject displayed a soil ingestion rate based on vanadium of approximately 11 grams/day (g/day) while all other (i.e., 7) tracers estimated less than 100 mg/day of ingested soil.[14]

While we have found ways to deal with input-output error (i.e., misalignment error), such as emphasizing studies of longer duration, using tracers with higher soil-to-food ra-

7. *See* Edward J. Stanek III & Edward J. Calabrese, *A Guide to Interpreting Soil Ingestion Studies. I. Development of a Model to Estimate the Soil Ingestion Detection Level of Soil Ingestion Studies*, 13 Reg. Toxicology & Pharmacology (1991) [hereinafter *Ingestion Studies I*]; Edward J. Calabrese & Edward J. Stanek III, *A Guide to Interpreting Soil Ingestion Studies. II. Qualitative and Quantitative Evidence of Soil Ingestion*, 13 Reg. Toxicology & Pharmacology 278-92 (1991) [hereinafter *Ingestion Studies II*].

8. *See Ingestion Studies I, supra* note 7; *Ingestion Studies II, supra* note 7.

9. Edward J. Calabrese et al., *How Much Soil Do Young Children Ingest: An Epidemiological Study*, 10 Reg. Toxicological Pharmacology 123-37 (1989) [hereinafter Calabrese et al., *How Much Soil*].

10. Scott Davis et al., *Quantitative Estimates of Soil Ingestion in Normal Children Between the Ages of 2 and 7 Years: Population-Based Estimates Using Aluminum, Silicon, and Titanium as Soil Tracer Elements*, 45 Archives Envtl. Health 112-22 (1990) [hereinafter Davis et al., *Quantitative Estimates*].

11. *See* Susan Binder et al., *Estimating Soil Ingestion: The Use of Tracer Elements in Estimating the Amount of Soil Ingested by Young Children*, 41 Archives Envtl. Health 341-45 (1986) [hereinafter Binder et al., *Estimating Soil Ingestion*].

12. *See* Edward J. Calabrese & Edward J. Stanek III, *High Levels of Exposure to Vanadium by Children Aged 1-4*, 28 J. Envtl. Sci. & Health 2359-71 (1993) [hereinafter Calabrese & Stanek, *High Levels of Exposure*].

13. *See* Edward J. Calabrese et al., *Soil Ingestion Estimates for Children Residing on a Superfund Site*, 36 Ecotoxicology & Envtl. Safety 123-37 (1997) [hereinafter Calabrese et al., *Soil Ingestion Estimates*].

14. *See* Calabrese & Stanek, *High Levels of Exposure, supra* note 12.

tios, and using fecal markers to signify the start and end of the soil ingestion observation period, dealing with the unknown source error challenge has been more problematic. Tracers with a potentially significant source error could be dropped from use in future studies as happened for vanadium. However, all trace elements have the potential for some source error once included within a particular study; the possibility of source error is problematic because it falsely elevates the soil ingestion estimates and distorts soil ingestion estimates especially at the 95 and 99 percentiles if the error is substantial. Source error has not been modulated by any of the improved study design features that are useful for input-output misalignment error. Except for excluding such tracers in subsequent studies, source error has been dealt with only at the level of statistical analysis where approaches can be employed to reduce its impact unbiasedly.[15]

Correcting for Error

Even though soil ingestion studies can have numerous and very large types of error of both a positive and negative nature, we have been able to identify, quantify, and correct for some of these errors. After such corrections, the degree of intertracer agreement improves. Such improvement is seen in Table 1 where corrections for various types of error have been made. This table provides information on the original mean soil ingestion estimates of six soil tracers (with barium and manganese not included because of their profoundly greater error). The table reveals that all tracers have error that can be identified, quantified, and corrected. However, the table indicates that the magnitude and type of error can vary markedly according to tracer. One can see that aluminum, silicon, and yttrium displayed modest positive and negative error, while titanium and vanadium were strikingly volatile, displaying high degrees of both positive and negative error, and zirconium displaying principally negative error. Such recognition is critical in the selection of tracers for future studies. However, the correcting of such error is important in order to maximize the value of a soil ingestion study.

The concept of error in soil ingestion studies and how large it could be was one of the great surprises encountered. As a result of the emerging concept of the potential for substantial error, considerable effort has been made to minimize such problems, as noted above, by considering the lengthening of studies to reduce the impact of misalignment error, using fecal markers to denote more precisely the start and finish of the study in order to link input with output and reduce misalignment (i.e., positive and negative error), and asking parents to exclude high tracer foods before and during the study in order to increase soil-to-food ratios (i.e., to reduce misalignment error). As a result of such changes, we have been able to reduce positive and negative misalignment error, and increase the likelihood of intertracer reliability of subject-soil ingestion estimates.

Table 1. Positive/Negative Error in Soil Ingestion Estimates in the Calabrese et al. (1989) Mass-Balance Study: Effect on Mean Soil Ingestion Estimate (mg/day)[a,b]

	Negative Error			Positive Error			
Trace Element	Lack of Fecal Sample on Final Study Day	Other Causes[c]	Total Negative Error	Total Positive Error	Net Error	Original Mean	Adjusted Mean
Aluminum	14	11	25	43	+18	153	136
Silicon	15	6	21	41	+20	154	133
Titanium	82	187	269	282	+13	218	208
Vanadium	66	55	121	432	+311	459	148
Yttrium	8	26	34	22	-12	85	97
Zirconium	6	91	97	5	-92	21	113

[a]How to read table: for example, aluminum as a soil tracer displayed both negative and positive error. The cumulative total negative error is estimated to bias the mean estimate by 25 mg/day downward. However, aluminum has positive error biasing the original mean upward by 43 mg/day. The net bias in the original mean was 18 mg/day positive bias. Thus, the original 156 mg/day mean for aluminum should be corrected downward to 136 mg/day.
[b]Values indicate impact on mean of 128 subject weeks in milligrams of soil ingested per day.
[c]Other possible causes may include: sample measurement error (e.g., Zr), other aspects of input/output misalignment in addition to a lack of fecal sample provided in the final study day.

Source: Calabrese and Stanek, 1995

15. *See* Edward J. Stanek III & Edward J. Calabrese, *Soil Ingestion Estimates Based on the Best Tracer Method*, 1 Hum. & Ecological Risk Assessment 133-56 (1995).

Available Soil Ingestion Studies: Recognizing Their Strengths and Limitations

There have been eight published soil ingestion studies on children[16] and two on adults.[17] Of the eight children studies, only four have involved a mass-balance protocol.[18] Both adult studies included a mass-balance protocol.[19] Several studies used only a few tracers,[20] while one study used only silicon.[21] Several studies by the University of Massachusetts researchers used up to eight tracers.[22]

The use of a mass-balance protocol has been noted above as critical in order to address the contributions of dietary quantities of tracers. Lack of a mass-balance protocol may significantly inflate soil ingestion estimates especially if that tracer is relatively high in the food or medicine ingested. The value of multiple tracers, as noted previously, is that they provide more independent estimates of the soil ingestion behavior. This helps to protect against erroneous conclusions based on a limited number of tracers, some of which may have significant error, especially source error. In addition, the use of multiple tracers will be advantageous if it is desired to differentiate soil from dust exposure. This issue, which has become progressively more significant in risk assessment, will be addressed later.

Several studies have collected daily samples over multiple days but lumped such daily samples together for a single chemical analysis for each participating child.[23] This lumping of daily samples into a single sample precludes the capacity to obtain daily estimates of soil ingestion. While reducing the impact of misalignment error, lumping prevents the estimation of such error. In contrast, other studies provided daily analyses of all samples.[24] Consequently, using such daily evaluations provides the capacity to address the issues of inter- and intra-subject daily variation.[25] In addition, a 1989 study by Calabrese et al. provided information on soil ingestion over two separate weeks so that interweek variation by children may be explored as well.[26] It should be noted that the collection and analysis of daily samples adds additional analytical chemistry costs to the project but that daily analyses add the capacity to identify, quantify, and correct for misalignment and source error.

Such a brief consideration of the general features of available soil ingestion studies reveals that they offer a wide degree of variation with respect to study protocols. While all studies, even those with significant study limitations, have contributed in important ways to the current understandings of soil ingestion, it is necessary to recognize the respective strengths and limitations of such studies in light of the above discussion and how they may be useful in the risk assessment process.

Table 2 provides a summary of the soil ingestion studies cited above with their respective soil ingestion values by specific tracer. It is important to know that each of the tracers within a study is estimating the same soil ingestion behavior among the same set of subjects over the same time. When values are considerably variable within a soil ingestion study, the issue of whether soil ingestion is detectable may be raised. While the "true" value never will be known, the basis for our above conclusion that the "true" amount of soil ingested by the average child was 30-60 mg/day is based on the above consideration for how we identify, quantify, and correct for various types of positive and negative error.[27] The values seen in Table 2 are "raw" values unadjusted for the presence of possible positive and negative error. However, our 30-60 mg/day estimate takes into account the various methods for correcting for misalignment and source error and is, therefore, an advance over a simple consideration of highly variable tracers within any particular study. Before the development of the error correction methodologies, it was not possible to discriminate among tracers.

16. *See* Binder et al., *Estimating Soil Ingestion*, *supra* note 11; Calabrese et al., *How Much Soil*, *supra* note 9; Edward J. Calabrese et al., *Soil Ingestion: A Concern for Acute Toxicity in Children*, 105 ENVTL. HEALTH PERSP. 1354-58 (1997) [hereinafter Calabrese et al., *Soil Ingestion*]; Calabrese et al., *Soil Ingestion Estimates*, *supra* note 13; Davis et al., *Quantitative Estimates*, *supra* note 10; Michael Wong, The Role of Environmental and Host Behavioral Factors in Determining Exposure to Infection With *Ascaris Lumbricoides* and *Trichuris Trichluta* (1988) (unpublished Ph.D. thesis, University of the West Indies) (on file with author) [hereinafter Wong, *The Role of Environmental and Host Behavioral Factors*]; Clausing et al., *A Method for Estimating Soil Ingestion in Children*, 59 INT'L ARCHIVES OF OCCUPATIONAL & ENVTL. MED. 73 (1987) [hereinafter Clausing et al., *A Method for Estimating Soil Ingestion in Children*]; J. H. Van Winjen et al., *Estimated Soil Ingestion by Children*, 51 ENVTL. RES. 147-62 (1990) [hereinafter Van Winjen et al., *Estimated Soil Ingestion by Children*].

17. *See* Edward J. Calabrese et al., *Preliminary Adult Soil Ingestion Estimates: Results of a Pilot Study*, 12 REG. TOXICOLOGY & PHARMACOLOGY 88-95 (1990) [hereinafter Calabrese et al., *Preliminary Adult Soil Ingestion Estimates*]; Edward J. Stanek III et al., *Soil Ingestion in Adults—Results of a Second Pilot Study*, 36 ECOTOXICOLOGY & ENVTL. SAFETY 249-57 (1997) [hereinafter Stanek et al., *Soil Ingestion in Adults*].

18. Although an additional reanalysis of the Binder study has attempted to account for food ingestion. *See* Kimberly M. Thompson & David E. Burmaster, *Parametric Distributions for Soil Ingestion by Children*, 11 RISK ANALYSIS 339-42 (1991). *See* Calabrese et al., *How Much Soil*, *supra* note 9; Calabrese et al., *Soil Ingestion*, *supra* note 16; Calabrese et al., *Soil Ingestion Estimates*, *supra* note 13; Davis et al., *Quantitative Estimates*, *supra* note 10.

19. *See* Calabrese et al., *Preliminary Adult Soil Ingestion Estimates*, *supra* note 17; Stanek et al., *Soil Ingestion in Adults*, *supra* note 17.

20. *See* Binder et al., *Estimating Soil Ingestion*, *supra* note 11; Davis et al., *Quantitative Estimates*, *supra* note 10; Calabrese et al., *Soil Ingestion*, *supra* note 16; Clausing et al., *A Method for Estimating Soil Ingestion in Children*, *supra* note 16; Van Winjen et al., *Estimated Soil Ingestion by Children*, *supra* note 16.

21. *See* Wong, *The Role of Environmental and Host Behavorial Factors*, *supra* note 16.

22. *See* Calabrese et al., *How Much Soil*, *supra* note 9; Calabrese et al., *Soil Ingestion*, *supra* note 16; Calabrese et al., *Soil Ingestion Estimates*, *supra* note 13; Stanek et al., *Soil Ingestion in Adults*, *supra* note 17.

23. *See* Binder et al., *Estimating Soil Ingestion*, *supra* note 11; Davis et al., *Quantitative Estimates*, *supra* note 10.

24. *See* Calabrese et al., *How Much Soil*, *supra* note 9; Calabrese et al., *Preliminary Adult Soil Ingestion Estimates*, *supra* note 17; Calabrese et al., *Soil Ingestion*, *supra* note 16; Calabrese et al., *Soil Ingestion Estimates*, *supra* note 13; Stanek et al., *Soil Ingestion in Adults*, *supra* note 17.

25. *See* Edward J. Stanek III & Edward J. Calabrese, *Daily Estimates of Soil Ingestion in Children*, 103 ENVTL. HEALTH PERSP. 276-85 (1995) [hereinafter Stanek & Calabrese, *Daily Estimates*].

26. *See* Calabrese et al., *How Much Soil*, *supra* note 9.

27. *See* Table 1 *supra*, where such corrections were made.

Table 2. Soil Ingestion Estimates in Children (mg/day) Uncorrected for Positive and/or Negative Error

	Binder et al. (1986)*		Van Wijnen et al. (1990)		Davis et al. (1990)		Calabrese et al. (1989) Stanek & Calabrese (1995)		Calabrese et al. (1997)	
Tracer Element	Mean	Median	Mean	Median	Mean	Median	Mean	Median	Mean	Median
Aluminum	181	121			40	25	153	29	2.7	-3.3
Silicon	184	136			82	59	154	40	-16.5	-18.2
Titanium	1834	618			246	81	218	55	-544.4	11.9
Barium							32	<0		
Manganese							<0	<0		
Vanadium							459	96		
Yttrium							85	9	42.3	32.1
Zirconium							21	16	19.6	-30.8
Cerium									116.9	44.9
Lanthanum									8.6	84.5
Neodymium									269.6	220.1
Best Tracer Method**							8	<0	65.5	20.1
Median of Best Four Tracers***							29	18	6.8	-2.4
Limiting Tracer Method										
Day-care Center			103	111						
Campers			213	160						

* Not adjusted for tracer intake from food.
** Diminishes input/output error.
*** Diminishes input/output and unknown source error.

Recent Advances

Differentiating Soil From Dust Ingestion

An important question confronting risk assessors is not only how much soil children ingest but also how much dust they ingest as well. This question is important because contaminant concentrations may differ importantly between soil and dust and because children spend a considerable proportion of their waking time indoors.[28] We have developed a method to estimate the amount of home dust that our subjects ingested.[29] The method involves the comparison of tracer ratio pairs (e.g., titanium/silicon, aluminum/silicon, etc.) from soil and dust with those for fecal samples for a specific individual.[30] For this method to be effective, there must be tracers that have quite different concentrations for soil and dust. If there are only very modest differences in tracer ratios between soil and dust, it will not be very likely

28. *See* Calabrese et al., *How Much Soil*, *supra* note 9.

29. *See* Edward J. Stanek III & Edward J. Calabrese, *Soil Ingestion in Children: Outdoor Soil or Indoor Dust?*, 1 J. Soil Contamination 1-28 (1992).

30. *See* Edward J. Calabrese & Edward J. Stanek III, *Distinguishing Outdoor Soil Ingestion From Indoor Dust Ingestion in a Soil Pica Child*, 15 Reg. Toxicology & Pharmacology 83-85 (1992).

that their respective contributions to the residual fecal tracer total will be differentiated adequately. Based on our original soil ingestion study,[31] we constructed 27 tracer ratio pairs from 8 soil tracers. This provides a substantial opportunity to distinguish soil from dust;[32] thus, the use of large numbers of soil tracers can be a very powerful factor in resolving the question of differentiating soil from dust.

For one child in the 1989 Calabrese et al. study, very large quantities (>20 g) of soil were ingested on 2 days.[33] For this soil pica child, it was possible to distinguish soil from dust unequivocally. In Table 3, we compare 18 tracer ratios from soil and dust in relation to the fecal samples. The key question is which medium (i.e., soil or dust) tracer ratios most closely resemble the fecal tracer ratios. For this child's sample, we were fortunate to have many tracers where the soil and dust were quite different in their ratio pair values. In all cases, the child's fecal sample ratios matched very closely those ratios seen in the soil sample rather than in dust. This provides strong evidence that the residual fecal tracers were principally of soil origin. By interpolation, one may estimate the relative contribution of soil versus dust to the residual fecal tracer quantity and then to how much soil and dust were ingested during the period of observation by that subject.

Table 3. Ratios of Soil, Dust, and Residual Fecal Samples in the Soil Pica Child

	Soil	Fecal	Dust	Estimated % of Residual Fecal Tracers of Soil Origin as Predicted by Specific Tracer Ratios
1. Manganese/Titanium	208.4	215.2	260.1	87
2. Barium/Titanium	187.4	206.2	115.8	100
3. Silicon/Titanium	148.1	136.7	7.5	92
4. Vanadium/Titanium	14.6	10.3	17.9	100
5. Aluminum/Titanium	18.4	21.1	13.3	100
6. Yttrium/Titanium	8.6	9.6	5.7	100
7. Manganese/Yttrium	24.3	22.4	45.9	100
8. Barium/Yttrium	21.9	21.4	20.4	71
9. Silicon/Yttrium	17.3	14.2	1.3	81
10. Vanadium/Yttrium	1.7	1.1	3.2	100
11. Aluminum/Yttrium	2.1	2.2	2.4	88
12. Manganese/Aluminum	11.3	10.2	19.5	100
13. Barium/Aluminum	10.2	9.8	8.7	73
14. Silicon/Aluminum	8.0	6.5	0.6	81
15. Vanadium/Aluminum	0.8	0.5	1.3	100
16. Silicon/Vanadium	10.1	13.3	0.4	100
17. Manganese/Silicon	1.4	1.6	34.7	99
18. Barium/Silicon	1.3	1.5	15.5	83
19. Manganese/Barium	1.1	1.0	2.2	100

Source: Calabrese and Stanek, 1992

31. *See* Calabrese et al., *How Much Soil*, *supra* note 9.
32. Note that a soil tracer study with only three tracers (e.g., Al, Si, and Ti) would only be able to derive three tracer ratio pairs (e.g., Al/Si, Al/Ti, Si/Ti).
33. *See* Calabrese et al., *How Much Soil*, *supra* note 9.

Estimating Daily Soil Ingestion Rates

Initial soil ingestion estimates provided a daily soil ingestion averaged over a time period.[34] This rate was simply the total estimated quantity of soil ingested divided by the total number of days observed. Thus, this did not offer any insight [into] the nature of variation within a subject [on] different days. In order to provide more realistic estimates of soil ingestion over a longer time frame than the study's duration, it is necessary to obtain estimates of soil ingestion on each day of the study for each subject.[35] These findings could then be modeled in order to estimate exposure over any duration desired.

Several years ago, we developed a novel method to estimate an individual day's soil ingestion for subjects and then used these values to estimate soil ingestion over a 365-day period.[36] The estimation of daily soil ingestion and subsequent extrapolation over a year were instructive because they provided the opportunity to estimate the number of days in a year that various proportions of the population would be predicted to ingest amounts of soil of interest (e.g., ≤200 mg, ≥500 mg, ≥1,000 mg, ≥5,000 mg, or ≥10,000 mg). As seen in Table 4, this exercise predicted that 33 percent of the children would have 1 to 2 days per year when they would ingest more than 10 g of soil while 16 percent of the children would ingest more than 1,000 mg on 35 to 40 days in a year. These values are model estimates based on the daily soil ingestion estimates and are likely to overestimate soil ingestion.[37] However, such daily estimates could be used with other models with different assumptions and therefore yield other predictive outcomes. The principal point is that with the capacity to provide daily estimates the risk assessor has greater capacity to address more biologically relevant exposure periods that are highly relevant for site-specific risk assessments.

Table 4. Estimated Percent of Children With Soil Ingestion Exceeding Daily Rates for Given Time Periods Per Year

Estimated No. of Days/Year With Soil Ingestion	Daily Rate of Soil Ingestion				
	>200 mg	>500 mg	>1 g	>5 g	>10 g
1-2	86	72	63	42	33
7-10	72	53	41	20	9
35-40	42	31	16	1.6	1.6

Source: Stanek and Calabrese, 1995

Soil Particle Size That Children Ingest

Many contaminants are associated with specific particle sizes found in soil.[38] Researchers typically have determined concentrations of trace elements in soil ingestion studies sieved to a diameter of 2 millimeters (mm). Knowledge of the soil particle sizes that children ingest may be a critical determinant in the exposure assessment process. In order to determine the particle size ingested, it is necessary to have two groups of tracers in soil: one whose concentration in soil is independent of particle size; the other being tracers whose concentration is particle-size dependent. In fact, tracers such as aluminum, silicon, and titanium are particle-size independent while the concentrations of cerium, lanthanum, and neodymium are highly dependent on particle size.[39] In the case of these three particle-size dependent trace elements, their concentrations increase markedly as the particles become finer (i.e., smaller in diameter). Moreover, as the particle size diminishes from 2 mm to 250 micrometers (μm) in diameter, the concentration increases from 2.5- to 4-fold for these three tracers. Because particles in the range of 50-100 μm in diameter are typically the ones that adhere to children's fingers,[40] and that children place their fingers frequently in their mouths,[41] children may be likely to ingest soil of relatively fine particle size.

Soil particles at a 2 mm diameter have a concentration of cerium, lanthanum, neodymium of one-half to one-quarter of that in the less than 250 μm range.[42] As a result, soil ingestion estimates are expected to be 2- to 4-fold higher for cerium, lanthanum, and neodymium when estimates use the 2 mm particle size. Once we started estimating soil ingestion according to particle size (50, 100, and 250 μm), the intertracer reliability of soil ingestion estimates markedly improved. The key feature in estimating particle size ingested is to determine the particle size where the intertracer variability is minimized to the greatest extent. This method works very well in the zone from 2 mm to 250 μm. There does not appear to be significant further concentration of the above three tracers (lanthanum, cerium, neodymium) at particle sizes below 250 μm (i.e., down to 50 μm diameter).[43] The available data suggest that the children were ingesting the finer particles but it was not possible to add further significant precision below the 250 μm diameter particle size.

In the particle size methodology, it is necessary to have tracers (i.e., gold standard tracers) that do not vary by particle size. These tracers will provide reliable estimates of soil ingestion regardless of the particle ingested. However, because contaminant concentrations may differ by particle size, it is valuable to include particle-size dependent tracers along with the gold standard tracers in soil ingestion studies. However, it would be ideal if tracer elements were available

34. *See* Binder et al., *Estimating Soil Ingestion, supra* note 11; Clausing et al., *A Method for Estimating Soil Ingestion in Children, supra* note 16; Calabrese et al., *How Much Soil, supra* note 9; Davis et al., *Quantitative Estimates, supra* note 10.

35. *See* Edward J. Stanek III et al., *A Caution for Monte Carlo Risk Assessment of Long-Term Exposures Based on Short-Term Exposure Study Data*, 4 Hum. & Ecological Risk Assessment 409-22 (1998).

36. *See* Stanek & Calabrese, *Daily Estimates, supra* note 25.

37. *See id.*

38. Steven C. Sheppard & Evenden, *Ecosystem Processes: Contaminant Enrichment and Properties of Soil Adhering to Skin*, 23 J. Envtl. Quality 604-13 (1994).

39. *See* Edward J. Calabrese et al., *The Effect of Particle Size on Soil Ingestion Estimates*, 24 Reg. Toxicology Pharmacology 264-68 (1996).

40. *See* Sheppard & Evenden, *supra* note 38.

41. *See* Edward J. Stanek III et al., *Prevalence of Soil Mouthing/Ingestion Among Healthy Children Aged 1 to 6*, 7 J. Soil Contamination 227-42 (1998).

42. *See* Calabrese et al., *Soil Ingestion, supra* note 16.

43. *See* Edward J. Stanek III et al., *Soil Ingestion Estimates for Children in Anaconda Using Trace Element Concentrations in Different Particle Size Fractions*, Hum. & Ecological Risk Assessment (forthcoming 1998).

that progressively became more concentrated down to about 25-40 μm so that the entire range of possible particle sizes that could be ingested could be evaluated.

Soil Pica Children

Most children ingest soil occasionally, with the average child ingesting about 30-60 mg/day. However, there is great variability among children with respect to soil ingestion. Likewise, some children are highly variable in their soil ingestion activities, displaying little propensity for soil ingestion on one day while ingesting copious amounts the next day. While there has not been any concerted focus on the soil pica child, the available data indicate that some children ingest over 50 g of soil on particular days.[44] In our investigations, we have observed a normal 2.5-year-old girl ingest 20 and 22 g of soil on 2 days of 1 consecutive 4-day period.[45] Another investigation by our group observed another young girl who ingested about 1 to 2 g of soil on four of seven consecutive days.[46] While it is true that some children will ingest large amounts of soil, it is far from certain whether soil pica is behavior that only a small subgroup displays over a limited number of years (e.g., one to six) or whether most children, on occasion, display this behavior or some combination of both behavioral patterns.[47]

The critical question concerns the significance of soil pica behavior for the public's health. This question was recently addressed, indicating that if children ingested as much soil on *only one day* that we have observed in our studies at the level of contamination that EPA has denoted as acceptable, the child would be in a lethally potential zone based on published human clinical toxicology reports for four chemicals (i.e., cyanide, phenol, fluoride, and vanadium).[48] In addition, for eight other agents, soil ingestion at a rate observed by us on a single day would be in a frank toxicity but nonlethal zone of responses.[49] These findings are extremely troublesome because the amount of soil presumed to be ingested has been observed in children and the amount of toxicant that could threaten the life of a child is based on published human responses. This acutely toxic response to a single soil ingestion episode requires no animal extrapolation commonly used in risk assessment. While there are issues of bioavailability that we could not address due to a lack of data, this factor is at least partially offset by the fact that minimal lethal doses were not yet determined. It seems troubling that national statewide cleanup standards have been established at levels where one day's exposure may result in a potentially lethal dose. Of considerable concern is the rapid reintegration of brownfields into commerce and possibly residential development, implying that the risks of such acutely lethal and toxic episodes occurring will increase. The impact of such an acute toxic event on the child's health, the child's family, and the public's confidence in state and federal agencies may be enormous. (See Table 5 on opposite page.)

Adult Soil Ingestion

The issue of adult soil ingestion has not received as much attention as that of children. While the rationale for this focus is intuitive, the risk assessment implications of soil ingestion in adults may be more significant than in children on a cumulative dose basis. For example, soil ingestion in young children may be anticipated over age 1 to 6 while post-early childhood covers many more years (e.g., 7 to approximately 70). Using an EPA framework, soil ingestion is grouped into children and adult values. For children, the assumed age has been from about 9 to 12 months of age, to 6 years of age. Adult values have been from 18 to 70 years. The intermediate age group of 7 to 17 has not been specifically addressed and has never been the object of soil ingestion investigations. While EPA derived a value of 200 mg/day for the upper 95 percentile of young children, they selected a value of 100 mg/day for adults. Based on this soil ingestion rate, it is easily seen that the cumulative dose in adults per person exceeds that seen over the years of early childhood. However, if exposure is adjusted for body weight differences, the exposure of a child over years 1-6 at 200 mg/day will exceed that of an adult at 100 mg/day from 18-70 years by almost 2-fold.

It should be noted that the 100 mg/day default value that EPA selected for adults was not based on any known adult human data published in the scientific literature at the time of its notification. It appears that the value of 100 mg/day was based on a reasonable general assumption that an adult would most likely ingest less soil than a child. However, how much less soil an adult was likely to ingest was less certain. For example, should the adult value have been 10 mg/day, 25 mg/day, or 50 mg/day, instead of 100 mg/day? Without data, such estimates are truly "professional" judgments at best and simply guesses at worst. Regardless of how they are characterized, there is substantial uncertainty about the default value.

Our adult validation studies assessed the capacity to "recover" soil in the feces that had been ingested in known amounts in capsules. The studies were designed to determine how close the mass-balance soil ingestion methodology would come to estimating soil capsule doses. If soil estimates were close to capsule doses, the studies would add confidence that the methodology was appropriate.

Two adult validation studies have been conducted.[50] The adult validation studies consisted of 1 week in which the subjects (i.e., 6 subjects in study 1; 10 subjects in study 2) ingested a blank capsule and then on alternating weeks on and off capsules with 100 and 500 mg/day (study 1) or 20, 100, and 500 mg/day (study 2). Thus, both studies had a "control" week in which no soil was given (i.e., first week of the study). For these two control weeks, soil ingestion rates could be estimated directly. However, we also had the opportunity to estimate soil ingestion on the other weeks of the studies after first subtracting the amount of soil ingested in each capsule from the fecal samples that the subjects had ingested. In this way, we could increase the number of adult subject-days that soil ingestion could be assessed.

44. *See* Wong, *The Role of Environmental and Host Behavioral Factors*, *supra* note 16.

45. *See* Edward J. Calabrese et al., *Evidence of Soil-Pica Behavior and Quantification of Soil Ingestion*, 10 HUM. & EXPERIMENTAL TOXICOLOGY 245-49 (1991).

46. *See* Calabrese et al., *Soil Ingestion*, *supra* note 16.

47. *See* Edward J. Calabrese et al., *Lead Exposure in a Soil Pica Child*, 28 J. ENVTL. SCI. & HEALTH, 353-62 (1993).

48. *See* Calabrese et al., *Soil Ingestion*, *supra* note 16.

49. *See* Table 5 *infra*.

50. *See* Study 1: Calabrese et al., *Preliminary Adult Soil Ingestion Estimates*, *supra* note 17; Study 2: Stanek et al., *Soil Ingestion in Adults*, *supra* note 17.

Table 5. Estimates of Acute Toxicity Associated With Soil Pica Episodes in Young Children at EPA Soil Screening Concentrations

Chemical	Soil Screening[a] Value (mg/kg soil)	Soil Intake (g soil/event)	Dose From Soil[b] (mg/kg body weight)	Lethal Dose (mg/kg body weight)	Reference	Nonlethal Toxic Dose (mg/kg body weight)	Effects	Reference
Antimony	31	5	0.01	ND	--	0.528	Nausea, vomiting	(14)
		25	0.06					
		50	0.12					
Arsenic	0.4[c]	5	0.002	1-3	(16)	1	Throat irritation, nausea and vomiting	(15)
		25	0.008					
		50	0.015					
Barium	5,500	5	2.1	43-57	(17)	2.86-7.14	Acute threshold for toxicity in adults	(16)
		25	10.6					
		50	21.2					
Cadmium	78	5	0.03	25	(18)	0.043-0.07	GI irritation and vomiting in children	(18, 19)
		25	0.15					
		50	0.3					
Copper	3,100*	5	1.2	14-429	(21)	0.09	Vomiting and diarrhea	(21)
		25	6.0					
		50	11.9					
Cyanide	1,600	5	0.6	0.5	(23)	ND		--
		25	3.1					
		50	6.2					
Fluoride	4,700*	5	1.8	4	(24)	0.04-3.0[d]	GI effects	(24)
		25	9.0					
		50	18.1					
Lead	400	5	0.2	ND	--	0.02	Decreased ALAD	(25)
		25	0.8					
		50	1.5					
Naphthalene	3,100	5	1.2	ND	--	~70[e]	Severe bladder pain and near blindness	(26, 27)
		25	6.0					
		50	11.9			109	Hemolytic anemia	
Nickel	1,600	5	0.6	570	(29)	0.009[e]	Contact dermatitis	(29)
		25	3.1					
		50	6.2					
PCP	3	5	0.001	17[f]	(31)	ND		--
		25	0.006					
		50	0.012					
Phenol	47,000	5	18.1	39[f]	(31,32)	14	GI effects	(31)
		25	90.4	10-50[g]				
		50	180.8					
Vanadium	550	5	0.2	0.86	(33)	ND		--
		25	1.1					
		50	2.1					

Abbreviations: ND, not determined (no acute toxicity doses in humans were identified); GI, gastrointestinal; ALAD, aminolevulinic acid dehydratase; PCP, pentachlorophenol.
a Values with an asterisk are from the EPA's *Risk-Based Concentration Tables, Region III* (11); values without an asterisk are from the EPA's *Soil Screening Guidance* (5).
b Calculated as (soil screening value × soil intake)/13 kg assumed body weight.
c This value may be below background levels in some parts of the United States. In such cases, the natural background value would be used.
d Estimated dose based on an assumed body weight of 35 kg.
e Estimated dose based on an assumed body weight of 70 kg.
f Estimated dose based on an assumed body weight of 59 kg.
g Estimated dose based on an assumed body weight of 5 kg for an infant.

Source: Calabrese et al., 1997

The number of subject-weeks can be increased by employing weeks when the subject ingested soil capsules. This increased the subject-weeks from 6 to 18 in study 1 and from 10 to 40 in study 2. Because the study protocol for study 1 measured subjects 4 days per week, while the protocol for study 2 measured subjects 7 days per week, the number of subject-days increased from 24 to 72 days in study 1 and from 70 to 280 days in study 2. Along with the advantage of increasing the number of days of soil ingestion exposure of subjects by including weeks that subjects ingested the capsule, including the soil capsule weeks also created the possibility for error if the total amount of ingested capsule soil could not be accounted for in the study data. By combining the number of adult subject-days with and without soil capsules, we achieved 352 adult subject-days on which to evaluate soil ingestion. The number of adult subject-days is a small fraction of the nearly 1,100 children subject-days available to University of Massachusetts investigators. In addition, the subject-weeks of other investigations [51] (i.e., they could not provide daily estimates because of combined daily samples) amounts to approximately another 300 subject values ranging from as short as 1 day to as long as 7 days. Regardless of how we combine the data, it is quite evident that adults have been studied much less than children. Also important to consider is that two children studies made strong attempts to obtain population-based random samples to enhance generalizability of the findings (albeit only from northern U.S. locations). [52] However, in the case of the adult validation studies, the subjects were drawn from the very restricted pool of University-associated employees and graduate students.

The adult investigations were conducted using identical study designs as in the children's studies because they were designed to validate the soil ingestion estimation protocol. Consequently, the adult studies are also susceptible to the same types of input-output misalignment error as well as source error as seen with the children's studies. As in the children's studies, these types of error could be identified, quantified, and corrected, but have not been addressed to date. The average soil ingestion rates surprisingly did not differ noticeably from that seen with children. Another surprise is that some adults, like children, display large amounts of soil ingestion (≥1,000 mg) on particular days. Thus, the concept of soil pica adults was raised for the first time.

Due to a more limited sample size as noted above, and the potential bias that the use of subject-days involving soil capsule ingestion involves, the degree of confidence in the adult data overall is less than that of the children. On the other hand, the adult data from a 1997 study by Stanek et al. was unique in following 10 adults over 28 days each. [53] This repeat measuring of soil ingestion (for up to one month) goes far beyond the eight days maximum observed for children [54] and may provide more detailed information on daily variation for selected individuals than any other study.

In a related matter, EPA has adopted a type of "occupational" exposure default value for soil ingestion of construction workers. This value of 480 mg/day has come to dominate the soil ingestion risk assessment process for many site-specific evaluations. [55] Again, as in the case of the original estimate of adult soil ingestion by EPA, there are no data on construction worker values. Given the experience of EPA's reducing 10,000 mg/day to 200 mg/day in light of data replacing "professional" judgment, it is hoped that a data-driven basis for such a critical default value for the risk assessment process will be embraced.

Pets and Wildlife

The mass-balance soil methodology also was used in studies to determine how much soil a female Irish Setter pet dog ingested per day. Over a consecutive 3-day period, the dog ingested 10-12 g/day. [56] In human terms, this is an enormous amount of soil, some 500-fold higher than EPA's assumed human exposure for soil ingestion for the upper 95 percentile. However, other reports by the U.S. Fish and Wildlife Service (FWS) have confirmed that copious soil ingestion is the rule for many species of birds and land mammals. [57] Yet, there has been little attention directed toward this issue despite the extensive development in the area of ecological risk assessment. The level of 10-12 g/day for the dog was about 1 to 2 percent of her diet. These values are similar for many species cited by the FWS and far less than other species. [58]

Conclusion

Over the past 12 years we have learned much about soil ingestion in children and how to design, conduct, and interpret studies of such behavior. There still remain significant gaps in our knowledge. The present record indicates that scientists have never studied soil ingestion in a southern state, in the inner city, over a period longer than eight days, or in more than one season. Whether soil ingestion rates will vary by region of the country, inner city versus suburban and rural, or by season is unknown, and remains to be evaluated. Thus, our national soil ingestion norms are extrapolations from one region of the country to others, from suburban to inner city and rural, and from one season (the summer or fall) to another. Despite the norms, scientists do not know how reliable the underlying assumptions are that suggest that these extrapolation procedures are appropriate. Even though the vast majority of available soil ingestion data is directed toward the "average" child, sufficient data exist indicating that some children can eat huge amounts of soil on some days, amounts that could theoretically lead to lethality with a one-time exposure from "acceptable" levels of some

51. *See* Binder et al., *Estimating Soil Ingestion*, *supra* note 11; Davis et al., *Quantitative Estimates*, *supra* note 10; Van Winjen et al., *Estimated Soil Ingestion by Children*, *supra* note 16.

52. *See, e.g.*, Davis et al., *Quantitative Estimates*, *supra* note 10; Calabrese et al., *Soil Ingestion*, *supra* note 16.

53. *See* Stanek et al., *Soil Ingestion in Adults*, *supra* note 17.

54. *See* Calabrese et al., *How Much Soil*, *supra* note 9.

55. Deborah M. Proctor et al., *Resolving Uncertainties Associated With the Construction Worker Soil Ingestion Rate: A Proposal for Risk-Based Remediation Goals*, 3 Hum. & Ecological Risk Assessment 299-304 (1997).

56. *See* Edward J. Calabrese & Edward J. Stanek III, *Resolving Intertracer Inconsistencies in Soil Ingestion Estimation*, 103 Envtl. Health Persp. 454-57 (1995).

57. *See* W. Nelson Beyer et al., *Estimates of Soil Ingestion by Wildlife*, 58 J. Wildlife Mgmt. 375-82 (1994).

58. *See id.*

soil contaminants. And yet, we know little about how common soil pica behavior is, how variable it is, or what its public health and regulatory implications are. Despite the above issues in humans, the hazards may be more acute in pets, farm animals, and wildlife where such creatures may commonly ingest >1 percent of their food as soil each day.

Similar concerns exist for soil ingestion rates for adults except that the database for them is much more limited. Much of the adult data are potentially confounded for being drawn from "adult validation" studies using soil capsules on volunteer adults. Despite these limitations, national norms have been adopted for assumed soil ingestion values of adult construction workers. Thus, considerable uncertainty exists for numerous aspects of adult and children soil ingestion.

What started as a simple journey 12 years ago, that is, to assess whether the EPA assumption of 10,000 mg/day should be applied for risk assessment purposes at Times Beach, Missouri, has become an incredibly interesting, yet, complex scientific issue that has required the development of novel methodologies, a recognition of our past interpretation limitations, the improvement and application of the findings to newer and more refined questions of public health interest and concern. While we have learned much on this journey, quantifying soil ingestion is much like other areas of scientific inquiry—a good study raises more questions than it answers. Hopefully, the newly focused interest in children's health will reinforce the need to clarify the role of soil ingestion in childhood exposures to toxic substances in the environment.